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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,951	03/28/2006	Jian-Ping Wu	3477-112	5581
<div>20792      7590      11/28/2007 MYERS BIGEL SIBLEY &amp; SAJOVEC PO BOX 37428 RALEIGH, NC 27627</div>				
			EXAMINER AUDET, MAURY A	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 11/28/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/538,951		WU ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Maury Audet		1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 July 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-41, 43 and 44 is/are pending in the application.
- 4a) Of the above claim(s) 31-41, 43 and 44 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 20 is/are allowed.
- 6) ☒ Claim(s) 1-19 and 21-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

The present application has been transferred from former Examiner Khana to the present Examiner.

Applicant's amendments and arguments filed in the response of 7/10/07 are acknowledged. Claims 1-30 remain examined on the merits, and claims 31-41, 43 and 44 remain withdrawn as drawn to non-elected subject matter.

#### ***Claim Rejections - 35 USC § 112 2nd***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 12, 13, and 26 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive.

Applicant has not amended the claims to "distinctly claim" what "w/w" the limitation is referencing. Applicant acknowledges that the specification defines w/w as enzyme/protein content; however, the claim remains unclear, as openly claimed by original presentation, as to what the "claimed invention" is referring to. It is suggested that Applicant simply positively claim that which w/w is argued to represent.

***Claim Rejections - 35 USC § 102***

Claims 1, 3-7, 10-11, and 14-17 were rejected under 35 U.S.C. 102(b) as being anticipated by Wu et al. (J. Agric. Food Chem. 49:501-506 (2002)), based in part on the art recognized teachings evidenced by Garrison et al. (US 4,174,075). Applicant's arguments, in combination with the present amendments, have been considered and are found persuasive over the art of record in the original 102 rejection. But only in-so-far as Applicant has amended the claims to "positively" claim that step a) must come before step b) and step a) and b) before step c); respectively. As the application of Wu et al. was based on the inherency of the previously open-ended method steps, the same inherency argument as to the now positively recited steps being in sequential order cannot unequivocally be maintained as before (i.e. that Wu et al. inherently carried out step a), followed by step b), and concluding with step c). Based on Applicant's amendments, the rejection is now properly made under 35 USC 103, under obviousness as opposed to inherency, in regards to the presently amended claimed invention.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claims 1, 3-7, 10-11, and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (J. Agric. Food Chem. 49:501-506 (2002)) *in view of* Garrison et al. (US 4,174,075), Eto et al. (J. Jpn. Soc. Nutr. Food Sci (1998), 51:355-359; cited by the Applicant in the IDS filed on February 21,2006), and further in view of Tzen et al. (Plant Physiol. (1993) 101:267-276).

The claimed invention (base claim 1) has now been amended to positively recite the sequential stepwise process of preparing an angiotensin converting enzyme (ACE) inhibitory peptide-containing hydrolysate comprising: a) contacting a substantially oil-free (i.e., defatted) seed meal or a flour with an organic solvent (thus, effecting a further extraction), b) separating the meal or flour of step (a) from the solvent, and c) treating the separated meal or flour of step (b) with at least one proteolytic enzyme to produce an ACE inhibitory peptide-containing hydrolysate as recited in claim 1. For this reason, this 103 rejection over the same claims previously rejected under 102 (and as premised in the discussion under the 102 rejection above), is properly based on Wu et al. in view of (rather than 'and') Garrison et al.

All the references were discussed in the previous action.

Wu et al. does not expressly teach the sequential steps of presently claimed steps a)-c) (claim 1, which all later claims directly or indirectly depend).

As discussed previously, Garrison et al. "teach defatting of oleaginous seeds rich in lipids with extraction using water-alcohol systems at temperature ranges from room temperature to the boiling point of the solvent to provide high quality protein."

Applicant had argued under the 102 rejection that the now amended, sequential steps of a)-c) are no longer “inherently” taught by Wu et al. This argument is found persuasive, even in view of the art recognized teachings exemplified by Garrison et al., which cannot remove the shortcomings of Wu et al. as concerns the issue of “inherency”. However, these arguments are only found persuasive as to the issue of whether Wu et al. expressly/inherently teaches the invention, but not as to the issue of obviousness as to whether the present invention is obvious over Wu et al. in view of the advantageous teachings of Garrison et al.

Secondly, Applicant argues that Wu et al. does not [expressly] discuss how the soy meal is defatted or any method of extraction of the soy meal with an organic solvent”. This is not found persuasive in view of the teachings of Garrison et al.

It would have been obvious at the time of the invention to arrive at the sequential steps for preparing an angiotensin converting enzyme (ACE) inhibitory peptide-containing hydrolysate in Wu et al., based on the advantageous teachings of Garrison et al., because the lack of express teachings by Wu et al. as to how the soy meal is defatted or the use of a solvent therein (as asserted by Applicant), is overcome when combined with Garrison et al., analogous art in the same field as Wu et al. Thus, the skilled artisan would have been motivated to combine the teachings of Wu et al. as to the use proteolytic enzymes (e.g. Alcalase) to prepare ACE inhibitory peptide-containing hydrolysates with the teachings of Garrison et al. as to the steps of defatting the soy meal, using a solvent therein, and arrive at the presently claimed sequential three-step process of carrying out the same.

Claims 1,2, 8-9, 12-13, 17-18, 19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (J. Agric. Food Chem (2001) 49: 501-506) in view of Garrison et al. (USPN 4,175,075) and Eto et al. (J. Jpn. Soc. Nutr. Food Sci (1998), 51:355-359; cited by the Applicant in the IDS filed on February 21,2006).

The references were all discussed in the previous action. In essence, the rejection has now been modified to state that the rejection is made based on Wu et al. "in view of" Garrison et al. rather than based on either Wu et al. or Garrison et al., as equal primary references. The modification was necessitated based on Applicant's amendment of claim 1 to positively recite that the three "sequential" steps. For all other reasons of record, the rejection is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. Specifically, applicant argues that Wu et al. fails to disclose each element of the present invention. This Examiner does not dispute this, hence the reliance on the combination of Garrison et al. and Eto et al. Applicant second argues that the latter two references fail to remedy the deficiencies of Wu et al. Applicant premises this argument on the grounds that the extraction step in Garrison et al. does not expressly teach that the water/alcohol solvent is part of and for the defatting process. This is not found persuasive because the skilled artisan, based on the art recognized use of solvents, would not have been recognized the teaching of Garrison et al. as to the beneficial use of solvents, not as a teaching away directed only to carbohydrate removal, but rather as a general teaching, like others in the art, that solvents may be used in such processes to carry out defatting of solutions as well, including that of soy meal, as presently claimed. Garrison et al. remains analogous art in the field of agricultural chemistry with that of Wu et al., and a skilled artisan in the field (PhD in the chemical arts, with agronomy emphasis)

would have been motivated to combine the teachings of Wu et al. with Garrison et al. to arrive at the present invention. Applicant also argues that Garrison et al. is not analogous art and teaches away from the present invention. This is not found persuasive for the reasons above; namely, Garrison et al. is in the agricultural protein arts, analogous art relied upon by the skilled artisan in agricultural protein chemistry and the teachings are not deemed to send the artisan away from the presently claimed steps (teaching away) as Applicant argues.

As to the amended claims under rejection, the previous Examiner's conclusion is maintained that it would have been obvious to one of ordinary skill in the art at the time the invention was made to make adjustments to conventional working conditions as merely a matter of judicious selection and routine optimization for providing a means for the expected result of proteolytic cleavage of proteins in soy meal in Wu et al., based on the advantageous teachings/suggestions in Garrison et al. and Eto et al., which the skilled artisan would have been motivated to combine based thereon and arrive at the presently claimed invention.

Claims 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (J. Agric. Food Chem (2001) 49: 501-506) in view of Garrison et al. (USPN 4,175,075) and Eto et al. (J. Jpn. Soc. Nutr. Food Sci (1998), 51:355-359; cited by the Applicant in the IDS filed on February 21, 2006), as applied to claims 1, 2, 8-9, 12-13, 17, 19 above, and further in view of Tzen et al. (Plant Physiol. (1993) 101:267-276).

The references were all discussed in the previous action. In essence, the rejection has now been modified to state that the rejection is made based on Wu et al. "in view of" Garrison et al. rather than based on either Wu et al. or Garrison et al., as equal primary references. The



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modification was necessitated based on Applicant's amendment of claim 1 to positively recite that the three "sequential" steps. For all other reasons of record, the rejection is maintained for the reasons of record. Applicant's arguments have been considered but are not found persuasive. In essence, Applicant appears to be arguing on page 15/16, over two paragraphs, that the flax and canola of Tzen et al. are inferior proteins to the soy of Wu et al., and thus, one of ordinary skill in the art would not have deemed said proteins to fall within relied upon teachings within the field of soy protein (Wu et al.) and as such would not combine the teachings of Tzen et al. with those of Wu et al., in view of Garrison et al. and Eto et al.; further because Tzen et al. does not mention soy protein in said study. This is not found persuasive, on at least two grounds: 1) the ordinary skilled artisan in protein chemist in agricultural protein chemistry is familiar with the properties and teachings within the field and the applicability of said teachings proteins within said field; and 2) Applicant has not addressed the combination of Wu et al., in view of the combined teachings of Garrison et al., Eto et al. and further in view of Tzen et al., necessitated by amendment. Thus, this combination renders obvious claims 20-30, even after amendment of the base claims to sequentially ordered steps.

***Allowable Subject Matter***

As to claim 20, Applicant's amendments and arguments thereto, are deemed persuasive. Following the amendment of claim 20 to a hydrolysate comprising only the peptide of Val-Ser-Val, and the amendment of claim 1, to which claim 20 depends, to the sequential method steps of:

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1. (Currently Amended) A process for preparing an angiotensin converting enzyme (ACE)inhibitory peptide-containing hydrolysate comprising:
  - a\_) contacting a substantially oil-free seed meal or a flour with an organic solvent,
  - b\_) separating the meal or flour of step (a) from the solvent, and
  - c\_)..treating the separated meal or flour of step (b) with at least one proteolytic enzyme to produce an ACE inhibitory peptide-containing hydrolysate.

Thus, claim 20 is no longer reasonably taught or suggested, based on the prior art of record.

### *Conclusion*

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Claim 20 is allowed.

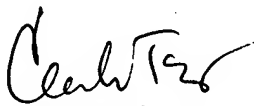
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 11/20/2007

  
Cecilia Tsang  
Supervisor